Best Practice Standards for managing Medicines Shortages in Secondary Care in England

Note. The principles apply to the rest of the UK but the document will require adapting for local structures in Scotland, Wales and N. Ireland

Introduction

Medicines shortages are occurring more frequently in the UK and globally for a variety of reasons. Although some of these have simple solutions, an increasingly large number have the potential to cause serious risk to patients. There is currently no national guidance to the NHS on how to manage shortages at a local level.

These standards are designed to provide advice to NHS hospitals in managing medicines shortages to minimise risk to patients.

Overarching Principles

Whilst the guiding principle must be that appropriate medicines should be available for all patients within an NHS Trust, the Chief Pharmacist should ensure that no action is taken within the Trust which could exacerbate a medicines shortage within the NHS. This may include for example the prohibition of selling medicines to third parties in accordance with the directions from the Chief Pharmaceutical Officer and /or stockpiling by individual Trusts when a shortage occurs.

Trusts should seek to work on a collaborative basis (e.g. “across regions”) to avoid duplication of work on risk assessments, procurement alternatives and production of clinical advice etc. NHS Trust Chief Pharmacists should work collaboratively to ensure that such medicines as are available during a shortage, are used for patients with the greatest clinical need.

Advice from Quality Assurance (QA) colleagues and UKMI should be available nationally when required. An example of regional working can be found in NHS South West (Stead D., Pharmacy Management Vol 26, 3, pp 8-11).

The NHS intends to develop and manage (itself or through a third party) a nationally available web site for medicines shortages information which should contain up to date information on shortages, their duration and recommended action where available

Whoever provides the initial information on a medicine shortage, be it Department of Health (DH), the Commercial Medicines Unit (CMU) or the Pharmaceutical Industry, this should be provided in a timely manner, with as much supporting information as possible, to allow trusts to take appropriate action to mitigate any effects on patient safety.

***[Note -** Whilst this document is not meant to be prescriptive, Chief Pharmacists will need to consider all the processes outlined below and ensure that they meet both the needs of the organisation and the risk to patients generated by each shortage].*

Standards for NHS Hospitals

1. The Chief Pharmacist is responsible for taking a leadership role in developing strategies and procedures for managing all aspects of medicines shortages

2. All NHS hospitals should have an up to date, written policy for managing medicines shortages.

3. A “clinical steering group” ideally consisting of a senior pharmacist, nurse and doctor should be established to oversee medicines shortages where appropriate.

4. When a shortage is identified, a designated senior pharmacist should conduct a fully documented risk assessment to evaluate the potential effect of the shortage. This assessment should take account of:

- The estimated duration of the shortage
- Usage figures
- The availability of suitable alternative products
- The potential risk to patients

*[**Note:** If trusts work collaboratively within a “region” then this assessment may not need to be carried out at each hospital].*

5. Not all shortages will need further action, but where the risk assessment supports further work on a long term/ critical shortage, the pharmacy should establish the stock on hand within its entire organisation and make an estimate of the time period this will cover. It is essential that this includes stock used through homecare or outpatient services provided by a third party. In order to manage this stock appropriately it may be advisable to hold the limited stock in a single area. Trust medicines procurement leads should take an active role in this process.

*[**Note:** Working collaboratively (e.g. within a region), limited stocks can be shared based on clinical need].*

6. Where limited stock leads to a restriction being placed on the use of a medicine, then this restriction should be discussed and agreed with the most relevant and appropriate senior doctor in the Trust (e.g. Medical Director, Clinical Director, Lead Speciality Clinician) with start and review dates, and should be communicated immediately to all relevant hospital staff. Communication of these restrictions is essential for ensuring patient safety and preventing medication errors.

7. Trusts should review their internal and external communications plans on a regular basis to ensure they are fit for purpose. The aim of the plan is to ensure that all hospital staff involved in the supply chain, and affected patients, where appropriate, are made fully aware of the situation. It is critical that patients/carers are counselled when a medicine shortage is likely to delay or compromise care.

8. Where a potential alternative medicine is available, then a named senior pharmacist should carry out a fully documented risk assessment of the alternative. [For a full list of potential issues to be assessed see Cousins D. et al www.pjonline.com/node/1104965.] If the alternative medicine involves the use/manufacture of an unlicensed product, then trusts should follow the guidance in MHRA MAL 14.

*[**Note:** This work should be supported by regional and/or national QA advice and additional clinical information on alternative products should be obtained from regional/national MI services].*

9. Once this assessment has been completed, then the relevant “clinical steering group” should agree the content of any resultant communication and must ensure that it reaches all appropriate hospital staff, including those on shift work. Trusts should also ensure that the Drugs and Therapeutics Committee (or equivalent) is notified and, through this committee, relevant information is passed on to local primary care organisations.

10. If any training or clinical advice is necessary as a result of the use of the alternative medicine, then the steering group should ensure that this takes place in a prompt and effective manner.

11. All medicines shortages have the potential to affect patient safety. Consideration should therefore be given as to the recording of such incidents on the Trust Risk Register or reporting through Trust incident reporting systems (e.g. Datix) and as such these will be notified to the Safe Medicines Practice Division of the National Commissioning Board Authority.

12. Following the resolution of a medicines shortage, the “clinical steering group” should meet/discuss and document the outcome, lessons learned and future actions and these should be communicated to all relevant hospital staff as appropriate.

13. NHS Trusts should keep an up to date log of shortages to include details of the shortage (this may help in identifying areas where shortages are most likely to occur), decisions taken, alternatives used and any new safeguards which have been introduced.

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Appendix 1.

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